FEB 7 2013

Appendix C 510(k) Summary

Applicant:	Spineology Inc. 7800 3rd Street N., Suite 600 Saint Paul, MN 55128 651-256-8500
Contact Person:	Bryan Becker
Date Prepared:	October 15, 2012
Trade Name:	Spineology Spinous Process Plate
Reason for This 510(k):	New device
Product Classification and Code:	Class II Medical Device, Product Code KWP, 21 CFR 888.3050, Spinal Interlaminal Fixation Orthosis
Predicate Device(s):	CD HORIZON SPIRE™, Medtronic Sofamor Danek (K032037, K043053, and K102886) and Lanx Aspen, Lanx (K103091)
Device Description:	The Spineology Spinous Process Plate is a non-pedicle fixation device that clamps bilaterally to the spinous processes. The three-part titanium device is provided sterile and not intended for stand-alone use.
Intended Use:	The Spineology Spinous Process Plate is a posterior, non-pedicle supplemental fixation device, intended for single level use in the non-cervical spine (T1 – S1). It is intended for single level plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: • Degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. • Trauma (i.e., fracture or dislocation) • Spondylolisthesis • Tumor The Spineology Spinous Process Plate is not intended for stand-alone use.
Summary of Technological Characteristics:	The device is shown to be substantially equivalent to the intended use, materials, configuration, and performance characteristics of the predicate products.
Testing:	Static (compression and torsion) and dynamic (compression and torsion) testing was performed per ASTM F1717. Static dissociation testing and push-out from foam (plate grip strength) was also completed.
Conclusion:	The information submitted in this premarket notification supports a determination that the Spineology Spinous Process Plate is substantially equivalent in technological characteristics and intended use to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Letter dated: February 7, 2013

Spineology Incorporated
% Mr. Bryan Becker
Regulatory Affairs Manager
7800 3rd Street North, Suite 600
Saint Paul, Minnesota 55128

Re: K123232
Trade/Device Name: Spineology Spinous Process Plate
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: January 4, 2013
Received: January 8, 2013

Dear Mr. Becker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix D Indications for Use Form

510(k) Number(if known): K123232

Device Name: The Spineology Spinous Process Plate

Indications for Use:

The Spineology Spinous Process Plate is a posterior, non-pedicle supplemental fixation device, intended for single level use in the non-cervical spine (T1 – S1). It is intended for single level plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions:

- Degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- Trauma (i.e., fracture or dislocation)
- Spondylolisthesis
- Tumor

The Spineology Spinous Process Plate is not intended for stand-alone use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123232